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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,165	08/22/2005	Hugo Ziegler	753-48 PCT/US	5604
7590 Hoffmann & Baron 6900 Jericho Turnpike Syosset, NY 11791-3550				
04/02/2008				
EXAMINER				
AUDET, MAURY A				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
04/02/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/530,165

**Applicant(s)**

ZIEGLER ET AL.

**Examiner**

MAURY AUDET

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-7 and 13-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date 7/1/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-7 and 13-16, as drawn to the general formula I, bearing a single amino acid Lysine at AA2 (as the compound of the invention) in the reply filed on 12/3/07 is acknowledged. The claims have been examined only in so far as it reads upon the elected invention. Claims 8-12 and 17-19 are withdrawn from consideration as being drawn to non-elected subject matter.

### ***Claim Objections***

Claims 1-7 and 13-17 are objected to because of the following informalities:

The claims have not been amended commensurate in scope with the elected invention of Lysine as AA2, deletion of AA3, etc.. The elected compound of the invention (Lysine) as part of the general formula I as not found to be reasonably taught or suggested by the prior art of record. Were the claims amended thereto, they would likely receive favorable consideration.

In line with the international search report (citing only 2 "A" references) and the written opinion findings of the International Authority in related PCT/CH/2002/000670:

"In light of the documents cited in the international search report, it is considered that the invention as defined in the claims meets the criteria mentioned in Article 33(1) PCT, i.e. it appears to be novel and to involve an inventive step. "

The closest prior art of record uncovered by this Office in the structure hereof on the elected single amino acid lysine compound, other than only Applicant and this application, is simply noted for the teaching of the chemical name and CN of the compound, which Applicant

can look up on STN if desired. The reference is merely noted, but not relied upon on (and hence the reference is not cited on an 892 or deemed necessary to forward to Applicant) was the dipeptide compound of (CN: 205439-22-1):

“Glycine, N6-[(1,1-dimethylethoxy)carbonyl]-N2-[(phenylmethoxy)carbonyl]-L-lysyl-2-[[2-(aminoiminomethyl)amino]ethyl]thio]-, (2S)-“

(cited in Hong et al. "Development of substrate for carboxypeptidase-B by employing thiaarginine peptides", Bulletin of the Korean Chemical Society (1998), 19(2), 189-193).

However, as Applicant has not claimed a dipeptide, but rather a single peptide, it was not entirely clear why this compound was returned, other than containing therein, the elected lysine compound as part of the internal structure. The latter was not found alone.

Appropriate correction is required.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAA, 3/31/08

/Maury Audet/

Examiner, Art Unit 1654